SECTION 1

INTRODUCTION

1.1 Legal Authority

The Pharmaceutical Manufacturing Point Source Category Effluent Limitations Guidelines and Standards are being finalized under the authority of Sections 301, 304, 306, 307, 308, and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendments of 1972, 33 U.S.C. 1251 et seq., as amended by the Clean Water Act of 1977, Pub. L. 95-217, and the Water Quality Act of 1987, Pub. L. 100-4), also referred to as "the Act."

1.2 Background

1.2.1 Clean Water Act

The Federal Water Pollution Control Act Amendments of 1972 established a comprehensive program to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters" (101(a)). To implement the Act, EPA is to issue effluent limitations guidelines, pretreatment standards, and new source performance standards for industrial dischargers.

These guidelines and standards are summarized briefly below:

1. Best Practicable Control Technology Currently Available (BPT) (304(b)(1) of the Act).

   BPT effluent limitations apply to all discharges from existing direct dischargers. BPT effluent limitations guidelines are generally based on the average of the best existing performance by plants of various sizes, ages, and unit processes within the category or subcategory for control of pollutants.

   In establishing BPT effluent limitations guidelines, EPA considers the total cost of achieving effluent reductions in relation to the effluent reduction benefits, the age of equipment and facilities involved, the processes used, process changes required, engineering aspects of the control technologies, nonwater quality environmental

impacts (including energy requirements), and other factors as the EPA Administrator deems appropriate (304(b)(1)(B) of the Act). The Agency considers the category- or subcategory-wide cost of applying the technology in relation to the effluent reduction benefits. Where existing performance is uniformly inadequate within a category or subcategory, BPT may be transferred from a different subcategory or category.

2. Best Available Technology Economically Achievable (BAT) (304(b)(2) of the Act).

In general, BAT effluent limitations guidelines represent the best existing economically achievable performance of plants in the industrial subcategory or category, based upon available technology. The Act establishes BAT as the principal national means of controlling the direct discharge of toxic and nonconventional pollutants to navigable waters. The factors considered in assessing BAT include the age of equipment and facilities involved, the process employed, potential process changes, and nonwater quality environmental impacts (including energy requirements) (304(b)(2)(B)). The Agency retains considerable discretion in assigning the weight to be accorded these factors. As with BPT, where existing performance is uniformly inadequate within a category or subcategory, BAT may be transferred from a different subcategory or category. BAT may include process changes or internal controls, even when these technologies are not common industry practice.

3. Best Conventional Pollutant Control Technology (BCT) (304(b)(4) of the Act).

The 1977 Amendments to the Act established BCT for discharges of conventional pollutants from existing industrial point sources. 304(a)(4) designated the following as conventional pollutants: biochemical oxygen demand (BOD_5), total suspended solids (TSS), fecal coliform, pH, and any additional pollutants defined by the Administrator as conventional. The Administrator designated oil and grease as an additional conventional pollutant on July 30, 1979 (44 FR 44501).

BCT is not an additional limitation, but replaces BAT for the control of conventional pollutants. In addition to other factors specified in 304(b)(4)(B), the Act requires that BCT limitations be established in light of a two-part "cost-reasonableness" test. American Paper Institute v. EPA, 660 F.2d 954 (4th Cir. 1981). EPA's current methodology for the general development of BCT limitations was issued in 1986 (51 FR 24974, July 9, 1986).

4. New Source Performance Standards (NSPS) (306 of the Act).

NSPS are based on the best available demonstrated control technology. New plants have the opportunity to install the best and most efficient production processes and wastewater treatment technologies. As a result, NSPS should represent the most stringent numerical values attainable through the application of

the best available control technology for all pollutants (i.e., conventional, nonconventional, and toxic pollutants). In establishing NSPS, EPA is directed to take into consideration the cost of achieving the effluent reduction and any non-water quality environmental impacts and energy requirements.

5. Pretreatment Standards for Existing Sources (PSES) (307(b) of the Act).

PSES are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of publicly owned treatment works (POTWs). The Act authorizes EPA to establish pretreatment standards for pollutants that pass through POTWs or interfere with POTWs' treatment processes or sludge disposal methods. The legislative history of the 1977 Act indicates that pretreatment standards are to be technology-based and analogous to the BAT effluent limitations guidelines for removal of toxic pollutants. For the purpose of determining whether to promulgate national category-wide pretreatment standards, EPA generally determines that there is pass through of a pollutant and thus a need for categorical standards if the nation-wide average percent removal of a pollutant removed by well-operated POTWs achieving secondary treatment is less than the percent removed by the BAT model treatment system.

The General Pretreatment Regulations, which set forth the framework for the implementation of categorical pretreatment standards, are found at 40 CFR Part 403. (Those regulations contain a definition of pass through that addresses localized rather than national instances of pass through and does not use the percent removal comparison test described above. See 52 FR 1586, January 14, 1987.)

6. Pretreatment Standards for New Sources (PSNS) (307(b) of the Act).

Like PSES, PSNS are designed to prevent the discharges of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of POTWs. PSNS are to be issued at the same time as NSPS. New indirect dischargers, like new direct dischargers, have the opportunity to incorporate into their plants the best available demonstrated technologies. The Agency considers the same factors in promulgating PSNS that it considers in promulgating NSPS.

1.2.2 304(m) Requirements

304(m) of the Clean Water Act (33 U.S.C. 1314(m)), added by the Water Quality Act of 1987, requires EPA to establish schedules for (I) reviewing and revising existing effluent limitations guidelines and standards ("effluent guidelines"), and (ii) promulgating new effluent guidelines. On January 2, 1990, EPA published an Effluent Guidelines Plan (55 FR 80), in which schedules were

established for developing new and revised effluent guidelines for several industrial categories. One of the industries for which the Agency established a schedule was the Pharmaceutical Manufacturing Point Source Category.

Natural Resources Defense Council, Inc. (NRDC) and Public Citizen, Inc., challenged the Effluent Guidelines Plan in a suit filed in U.S. District Court for the District of Columbia (NRDC et al. v. Reilly, Civ. No. 89-2980). The plaintiffs charged that EPA's plan did not meet the requirements of 304(m). A Consent Decree in this litigation was entered by the Court on January 31, 1992. The terms of the Consent Decree are reflected in the Effluent Guidelines Plan published on September 8, 1992 (57 FR 41000). This plan required, among other things, that EPA propose effluent guidelines for the pharmaceutical manufacturing category by January, 1994 and take final action on these effluent guidelines by August, 1995. Recently EPA filed an unopposed motion requesting an extension of time until July 30, 1998 for the Administrator to sign the final rule.

1.2.3 Pollution Prevention Act

The Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13101 et seq., Pub. L. 101-508, November 5, 1990), "declares it to be the national policy of the United States that pollution should be prevented or reduced whenever feasible; pollution that cannot be prevented should be recycled in an environmentally safe manner wherever feasible; and disposal or release into the environment should be chosen only as a last resort..." (See 6602; 42 U.S.C. 13101(b)).

1.2.4 Prior Regulation of the Pharmaceutical Manufacturing Category

EPA promulgated interim final BPT regulations for the Pharmaceutical Manufacturing Point Source Category on November 17, 1976 (41 FR 50676; 40 CFR Part 439 Subparts A - E). The BPT effluent guidelines established limitations for BOD_5, chemical oxygen demand (COD), TSS, and pH for wastewaters discharged by the extraction, the mixing/compounding and formulation, and the research subcategories and limitations for BOD_5, COD, and pH for wastewaters discharged by the fermentation and the chemical synthesis subcategories.

On November 26, 1982, EPA proposed regulations applicable to the Pharmaceutical Manufacturing Point Source Category (47 FR 53584) which proposed to modify and expand upon the November 17, 1976 regulations. EPA proposed the following:

- To modify the existing BPT TSS effluent limitations guidelines for the extraction, mixing, compounding and formulating, and research subcategories;
- To extend these revised BPT TSS effluent limitations guidelines to the fermentation and chemical synthesis subcategories;
- To modify the existing BPT COD effluent limitations guidelines for the fermentation, extraction, chemical synthesis, mixing/compounding and formulation, and research subcategories;
- To propose BPT cyanide effluent limitations guidelines for the fermentation, extraction, chemical synthesis, and mixing/compounding and formulation subcategories;
- To propose BAT COD and cyanide effluent limitations guidelines for the fermentation, extraction, chemical synthesis, and mixing/compounding and formulation subcategories;
- To propose BCT BOD_5, TSS and pH effluent limitations guidelines for the fermentation, extraction, chemical synthesis, and mixing/compounding and formulation subcategories;
- To propose BOD_5, COD, TSS, cyanide and pH NSPS for the fermentation, extraction, chemical synthesis, and mixing/compounding and formulation subcategories; and
- To propose cyanide PSES and PSNS for the fermentation, extraction, chemical synthesis, and mixing/compounding and formulation subcategories.

On October 27, 1983 (48 FR 49808), EPA promulgated portions of the November 26, 1982 proposal, proposed additional changes, and postponed portions of the proposed rule. This final rule included the following:

- Promulgation of BPT TSS limitations for all subcategories equal to a multiple of 1.7 times the existing BPT BOD_5 limitations;

- Promulgation of alternative BPT BOD_5 and COD concentration-based limitations for the extraction, mixing/compounding and formulation, and research subcategories (such alternative limitations were not deemed necessary for the fermentation and chemical synthesis subcategories because the available data indicated that raw loads were sufficiently high at these subcategory plants that limitations as low as the alternative limitations would not be required under BPT);

- Promulgation of BPT, BAT, NSPS, PSES, and PSNS for cyanide based on monitoring either in-plant after cyanide destruction or end-of-pipe after cyanide destruction and biological treatment for all but the research subcategory;

- Promulgation of pH NSPS for all but the research subcategory;

- Proposal of revised BOD_5 and TSS NSPS based on end-of-pipe filtration in combination with advanced biological treatment for all but the research subcategory;

- Postponement of a final decision on appropriate BAT limitations and NSPS for COD until a later date; and

- Postponement of BCT limitations until promulgation of the general methodology for determining appropriate levels of conventional pollutant control under BCT.

The October 27, 1983 preamble also included a discussion of BAT effluent limitations guidelines, NSPS, PSES, and PSNS for Toxic Volatile Organics (TVOs). The Agency decided, at that time, not to establish regulations controlling the discharge of volatile priority pollutants from pharmaceutical manufacturing plants based on certain provisions of the previous (1976) Settlement Agreement with NRDC, lack of data documenting harmful discharges or POTW pass-through of TVOs, and concern over the costs for treatment. However, the Agency obtained new data regarding the treatment of methylene chloride at a pharmaceutical manufacturing plant during a sampling study in which both the plant and EPA participated and began reconsidering its policy on regulating volatile priority pollutants. On September 9, 1985 (50 FR 36638), the Agency published a Notice of Availability and request for comments for the Pharmaceutical Manufacturing Point Source Category; Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards (which included the new study data). This notice

requested comments on the treatment of TVOs by steam stripping, pretreatment of wastewaters, and any information about changes in solvent usage and facility flows and treatment operations.

On December 16, 1986 (51 FR 45094), the Agency published a final rule for BCT BOD_5, TSS, and pH effluent limitations guidelines for all but the research subcategory. This final rule set the BCT effluent limitations guidelines equal to the existing BPT BOD_5, TSS, and pH effluent limitations guidelines.

In 1989, EPA withdrew the proposed NSPS for BOD_5 and TSS over concern for the cost-effectiveness of TSS control for Subcategories B and D.

On May 2, 1995 (60 FR 21592), EPA proposed regulations applicable to the Pharmaceutical Manufacturing Point Source Category which proposed to modify and expand upon the 1983 and 1986 final regulations. EPA proposed the following:

- To revise the existing BPT BOD_5, TSS, and cyanide effluent limitations guidelines for the fermentation, extraction, chemical synthesis, and mixing/ compounding and formulation subcategories;
- To set BCT equal to the revised BPT for BOD_5 and TSS for the same set of subcategories;
- To propose BAT COD, cyanide, priority, and nonconventional pollutant effluent limitations guidelines for the fermentation, extraction, chemical synthesis, and mixing/compounding and formulation subcategories;
- To propose BOD_5, COD, TSS, cyanide, priority, and nonconventional NSPS for the fermentation, extraction, chemical synthesis, and mixing/ compounding, and formulation subcategories; and
- To propose cyanide, priority, and nonconventional PSES and PSNS for the fermentation, extraction, chemical synthesis, and mixing/compounding and formulation subcategories.

Based on comments on and data EPA received in response to the May 2, 1995 proposal, and subsequent follow-up analysis, the Agency presented potential revisions to the proposal

regulatory options under the CWA in the April 2, 1997 (62 FR 15753) Proposed Maximum Achievable Control Technology (MACT) Standards for the Pharmaceutical Manufacturing Industry. EPA published a Notice of Availability (NOA) on August 8, 1997 (62 FR 42732). EPA published this Notice in order to allow public comment on the data received since the May 2, 1995 CWA proposal, further develop and revise options for the control of the VOCs that were presented in the April 2, 1997 CAA MACT proposal, and to suggest responses to some comments on the 1995 CWA proposal.

1.3 Scope of Final Regulations

The final regulation covers the fermentation, extraction, chemical synthesis, and mixing, compounding and formulating subcategories of the pharmaceutical manufacturing industry. EPA is promulgating the following:

- Revised BPT effluent limitations guidelines for COD for Subcategories A, B, C and D;
- BCT effluent limitations guidelines for BOD_5 and TSS equal to the existing BPT limitations for BOD_5 and TSS;
- BAT effluent limitations guidelines for COD, ammonia, and 30 organic pollutants at Subcategories A and C;
- BAT effluent limitations guidelines for COD for Subcategories B and D;
- NSPS effluent limitations guidelines for BOD_5, COD, and TSS at Subcategories A, B, C, and D. Additionally, NSPS effluent limitations guidelines for ammonia and 30 organic pollutants at Subcategories A and C;
- PSES and PSNS effluent limitations guidelines for ammonia and 23 organic pollutants at Subcategories A and C; and
- PSES and PSNS effluent limitations guidelines for 5 organic pollutants at Subcategories B and D.

Additionally, EPA is clarifying the existing regulation for cyanide at Subcategories A and C, and withdrawing the existing regulation for cyanide at Subcategories B and D. These final effluent

limitations guidelines and standards do not cover discharges generated from the research subcategory of the Pharmaceutical Manufacturing Point Source Category.